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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,206	06/26/2003	Daniel J. Potter	11536US.00	7328
33486 7590 01/29/2007 HEIMBECHER & ASSOC., LLC P O BOX 33 HAMEL, MN 55340-0033			EXAMINER YABUT, DIANE D	
			ART UNIT 3734	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/609,206

Applicant(s)

POTTER ET AL.

Examiner

Diane Yabut

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 December 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 May 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 26 December 2006 has been entered.

Claim Objections

2. Claim 10 is objected to because of the following informalities: It reads "along an said" on line 9 of Claim 10 and should be changed to --along said--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1-5, 9-11, and 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Mueller, Jr. (U.S. Patent No. **4,938,220**) in view of **Norlander** (U.S. Patent No. **6,562,049**) and **Makower** (U.S. Patent No. **5,830,222**).

Claims 1 and 9: Mueller, Jr. discloses a sheath body **19**, a radiopaque marker **10** located at a distal end of said sheath body, wherein radiopaque marker abuts said sheath, said radiopaque marker comprising a substantially cylindrical marker body, and at least one longitudinally extending marker score line, or notch, **12** running substantially along a length of said radiopaque marker (Figures 1-3, col. 1, lines 13-42). It is noted that Mueller, Jr. mentions that continuous radiopaque bands interfere with catheter functions, although here Mueller is referring to "bands of radiopaque material" and not score lines *on* the radiopaque marker. Mueller, Jr. discloses the claimed device except for the sheath body comprising a first longitudinally extending sheath score line running substantially along a length of said sheath body, and a score line or notch that allows said radiopaque marker to be split into two or more pieces along said at least one marker score line.

Norlander teaches sheath score lines **46** and further discloses that radiopaque materials may be incorporated into the splittable sheath or may be made of a separate band member (Figures 6-10, 12; col. 2, lines 8-15, col. 6, lines 61-67; col. 8, lines 31-43; col. 10, lines 63 to col. 11, line 4). It would have been obvious to one of ordinary skill in the art at the time of invention to modify Mueller, Jr. to include the splittable sheath, which may be made of radiopaque materials, as taught by Norlander, since it was

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known in the art that score lines or slits on tubular members increases flexibility and therefore facilitates removal from catheters or leads after deployment.

Makower teaches a score line or notch that allows a radiopaque marker to be split into two or more pieces along said at least one marker score line (col. 4, lines 4-15). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a score line that allows for said radiopaque marker to be split into two or more pieces, as taught by Makower, to Mueller, Jr. since it was known in the art that score lines prevent undesirable splitting until it is necessary to do so, in which case the tubular member may then be split or separated into two pieces by a certain amount of applied force.

Claims 2-4 and 10: Mueller, Jr. and Makower disclose the claimed device including first and second edges or score lines **13** (Figure 1, Mueller, Jr.) except for a second sheath score line running substantially along said length of said sheath body, wherein first and second sheath score lines are located on an exterior surface of said sheath body, and a second marker notch running substantially along said length of said radiopaque marker.

Norlander teaches first and second sheath score lines running substantially along said length of said sheath body, wherein first and second sheath score lines are located on an exterior surface of said sheath body and on opposite sides of said sheath body (Figures 6-8). Mueller teaches first and second edges or score lines **13** (Figure 1). Although Norlander does not have a second marker notch running substantially along said length of said radiopaque marker and first and second notches being located

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approximately opposite one another along said marker body, it would have been obvious to one of ordinary skill in the art at the time of invention to provide second sheath or marker score lines or notches/gaps, as taught by Norlander, to Mueller, Jr. and Makower since it was known in the art that multiple score lines facilitate removal of the sheath, marker, or other tubular members in that they can be split when positioned at different orientations or when one score line is not easily accessible on the opposite side.

Claims 5, 11, and 17: Mueller, Jr., Norlander, and Makower disclose the claimed device including said radiopaque marker comprising a first marker portion and defining a gap (Figure 1, Mueller, Jr.), except for said first sheath score line and said first marker score line, or notch, being aligned, and said second sheath score line and second marker score line, or notch/gap, being aligned. However, the combined device of Mueller, Jr., Norlander and Makower is capable of having aligned score lines in that the radiopaque marker can simply be rotated around the sheath until the score lines are aligned, and it would have been obvious at the time of invention to do so in order to efficiently remove both the sheath and the radiopaque marker from the catheter or lead simultaneously.

Claim 18: Mueller, Jr. discloses the gap running along an entirety of said first marker portion (Figures 1-2).

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5. Claims 6-8, 12-16, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Mueller, Jr.** (U.S. Patent No. **4,938,220**), **Norlander** (U.S. Patent No. **6,562,049**) and **Makower** (U.S. Patent No. **5,830,222**), as applied to Claims 5, 11, and 17 above, and further in view of **Lee** (U.S. Patent No. **6,520,934**).

Claims 6-8, 12, and 19: Mueller, Jr., Norlander, and Makower disclose the claimed device including said radiopaque marker being embedded in or within said sheath body, and first and second marker portions being completely embedded in said sheath body (see paragraph 4 above, esp. col. 10, lines 63 to col. 11, line 4, Norlander), except for said radiopaque marker being located within said sheath body, and said radiopaque marker being thermally bonded to said sheath body.

Lee teaches a radiopaque marker being located within said sheath body, and said radiopaque marker being thermally bonded to said sheath body (col. 1, lines 32-37). It would have been obvious to one of ordinary skill in the art at the time of invention to provide a thermally bonded radiopaque marker to the sheath body, as taught by Lee to Mueller, Jr., Norlander, and Makower since it was known in the art that thermally bonding markers to sheaths prevents undesirable relative movement, which would complicate the deployment process.

Claims 13-16: Mueller, Jr., Norlander, and Makower disclose the claimed device except for said first marker notch being V-shaped or U-shaped, the notch comprising first and second sidewalls, said first and second sidewalls substantially parallel to one another, and a base wall joining said first and second side walls, said base wall substantially perpendicular to said first and second side walls. However, according to

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Merriam-Webster's Online Dictionary, "notch" is defined as a "V-shaped indentation" or "a rounded indentation," and therefore it would have been obvious to implement the above limitations to the notch of the combined device of Mueller, Jr., Norlander, and Makower.

Claim 20: Mueller, Jr. discloses said radiopaque marker being made from a material from the group consisting of a particulate-laden polymer, barium sulfate, gold, platinum, and tungsten (col. 2, lines 31-35).

Claim 21: Mueller, Jr. discloses said first marker portion comprising a first marker half and said second marker portion comprising a second marker half (Figure 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "MJ Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER